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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Gary R. McLuen

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EXAMINER

HANDY, DWAYNE K

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

09/17/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/742,803	Applicant(s) MCLUEN ET AL.	
	Examiner DWAYNE K. HANDY	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-30,35-38,40,42,44-48 and 50-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-30,35-38,40,42,44-48 and 50-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/04/10 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 27-30, 35-38, 40, 42, 44-48 and 50-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35-55 of copending Application No. 12/154,880. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 35-55 of the '880 Application recite a vial or plurality of vials having the features of the vials recited in the instant claims. The claims of the '880 Application also recite an additional cartridge element. Claims 35-55 of the '880s Application, then, fully encompass the scope of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by McGraw et al. (5,609,826).

6. Claims 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Zuckermann et al. (5,609,826).

7. Claims 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Cargill et al. (5,609,826).

These rejections were maintained in the previous Office Action (mailed 03/04/10). They remain in effect. Please see Response to Arguments below.

Inventorship

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 27-29, 35-38, 40, 42, 44, 52 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGraw et al. (5,368,823).

11. Claims 27-29, 35, 36, 38, 45-48, 50-54, 56, 57 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zuckermann et al. (5,240,680).

12. Claims 27-30, 35, 36, 38, 45-48 and 50-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cargill et al. (5,609,826).

These rejections were maintained in the previous Office Action (mailed 03/04/10). They remain in effect. New claim 62 has been rejected under Cargill. Please see Response to Arguments below.

Response to Arguments

13. Applicant's arguments filed 06/04/10 have been fully considered but they are not persuasive.

McGraw

14. Applicant has argued that McGraw does not teach a protruding support (Page 10 of Arguments). This feature is beyond the scope of all claims except for claim 62 - as only claim 62 contains this feature. Claim 62 has not been rejected under McGraw.

15. Applicant has argued that the interior wall does not provide the support for the frit (Page 10 of Arguments). The Examiner respectfully disagrees and directs Applicant to Figure 6 which shows the frit (9) supported by the sidewalls in the tapering portion in the bottom of the vial.

16. Applicant has also argued that McGraw does not teach vial body that tapers from the top opening to the bottom opening. Applicant has also argued that the taper is critical as it makes possible the compression and seal of the frit in the vial (Pages 12-13 of Arguments). The Examiner disagrees that this is sufficient to overcome the previous

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103 rejection under McGraw. As previously noted above, Figure 6 of McGraw shows the frit (9) supported by tapering side walls. This tapering portion - while not extending all the way to the top of the vial – still provides the same function as the tapering walls of the instant vial. This difference in the degree of taper is a difference in shape that still provides the same function – holding the frit securely between the tapered walls of the vial - as in the instant vial.

17. Applicant has argued McGraw does not have a support that has a precise dimension that provides a pressure tight seal around the vial when placed in a cartridge. Applicant has also argued that McGraw does not teach a direct fit (Pages 14-22 of Arguments). The Examiner directs Applicant to Paragraphs 14-19 of the Office Action mailed 09/18/09 which addresses this argument.

Zuckermann

18. Applicant has argued that Zuckermann does not teach a protruding support (Page 23 of Arguments). This feature is beyond the scope of all claims except for claim 62 - as only claim 62 contains this feature. Claim 62 has not been rejected under Zuckermann.

19. Applicant has argued that the vial of Zuckermann lacks any tapering (Page 23 of Arguments). The Examiner respectfully disagrees and directs Applicant to Figure 3 of

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Zuckermann which shows the frit (27) supported by the sidewalls in a tapering portion in the bottom of the vial.

20. Applicant has also argued that Zuckermann does not teach vial body that tapers from the top opening to the bottom opening. Applicant has also argued that the taper is critical as it makes possible the compression and seal of the frit in the vial (Pages 23-26 of Arguments). The Examiner disagrees that this is sufficient to overcome the previous 103 rejection under Zuckermann. As previously noted above, Figure 3 of Zuckermann shows the frit (27) supported by tapering side walls. This tapering portion - while not extending all the way to the top of the vial – still provides the same function as the tapering walls of the instant vial. This difference in the degree of taper is a difference in shape that still provides the same function – holding the frit securely between the tapered walls of the vial - as the instant vial.

21. Applicant has argued Zuckermann does not have a support that has a precise dimension that provides a pressure tight seal around the vial when placed in a cartridge. Applicant has also argued that Zuckermann does not teach a direct fit (Pages 26-36 of Arguments). The Examiner directs Applicant to Paragraph 16 of the Office Action mailed 09/18/09 which addresses this argument.

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Cargill

22. Applicant has argued that Cargill does not teach a protruding support (Page 37 of Arguments). The Examiner respectfully disagrees and directs Applicant to Figure 2A of Cargill. In Figure 2A, Cargill shows a vial having a protruding support (128).

23. Applicant has argued that the narrowed portion of Cargill does not provide the function of retaining the support and frit (Page 38 of Arguments). The Examiner respectfully disagrees and directs Applicant to Figure 2A of Cargill which shows the frit (124) retained by the narrow portion (annular bead – 126) and the tapered bottom of the vial. See also column 8, lines 5-10 of Cargill which states “Lower portion 114 [of the vial] preferably also includes an annular bead 126 to retain frit 124 when it is pressed into place”.

24. Applicant has argued that Cargill lacks any significant tapering. Applicant has also argued that the taper is critical as it makes possible the compression and seal of the frit in the vial (Pages 38-40 of Arguments). The Examiner disagrees that this is sufficient to overcome the previous 103 rejection under Cargill. As previously noted above, Figure 2A of Cargill shows the frit (124) supported by a bead and tapering side walls. This taper in Cargill - while not extending all the way to the top of the vial – still provides the same function as the tapering walls of the instant vial. This difference in the degree of taper is a difference in shape that still provides the same function – holding the frit securely between the tapered walls of the vial - as the instant vial.

25. Applicant has argued Cargill does not have a support that has a precise dimension that provides a pressure tight seal around the vial when placed in a cartridge. Applicant has also argued that Cargill does not teach a direct fit (Pages 26-36 of Arguments). The Examiner directs Applicant to Paragraph 17 and 18 of the Office Action mailed 09/18/09 which addresses this argument.

Conclusion

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DWAYNE K. HANDY whose telephone number is (571)272-1259. The examiner can normally be reached on M-F 11:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dwayne K Handy/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

September 12, 2010